Saskatchewan Health

Drug Plan and Extended Benefits Branch

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SASKATCHEWAN FORMULARY COMMITTEE BULLETIN UPDATE TO THE 57th EDITION OF THE SASKATCHEWAN FORMULARY

The following listings are effective **October 1, 2007** unless otherwise indicated.

NEW FULL FORMULARY LISTINGS:

- blood glucose test strip, strip, (Ascensia Breeze 2-BAY)
- isopropyl myristate, topical solution, 50% (Resultz-ATA)
- ramipril/hydrochlorothiazide, tablet, 2.5mg/12.5mg, 5mg/12.5mg, 10mg/12.5mg, 5mg/25mg, 10mg/25mg (Altace HCT-AVT)
- valsartan, tablet, 320mg (Diovan-NVR)

NEW EXCEPTION DRUG STATUS (EDS) LISTINGS:

- abatacept, powder for solution, 250mg/vial (Orencia-BMY)
  For the treatment of severely active rheumatoid arthritis when used in combination with DMARDs (unless these agents are contraindicated) in patients who have failed to respond to an adequate trial of an anti-TNF agent. This drug should **NOT** be used **in combination** with other anti-TNF agents. The Committee supports the CEDAC recommendation to list this product.
- lanreotide acetate, injection, 60mg, 90mg, 120mg/syringe (Somatuline Autogel-TCI)
  For the treatment of acromegaly. The Committee supports the CEDAC recommendation to list this product.
- rituximab, injection, 10mg/mL (Rituxan-HRL)
  For the treatment of severe rheumatoid arthritis when used in combination with methotrexate in adult patients who have failed to respond to an adequate trial of an anti-TNF agent. Rituxan should not be used concomitantly with anti-TNF agents.

NEW STRENGTHS/DOSAGE FORMS OF CURRENTLY LISTED EDS DRUGS:

The current EDS criteria will apply to the following:

- atazanavir SO4, capsule, 300mg (Reyataz-BMY)

THE DRUGS LISTED BELOW WILL BE APPROVED UNDER EDS FOR THE FOLLOWING ADDITIONAL CRITERIA:

- alendronate sodium, oral solution, 70mg/75ml (Fosamax-MSD)
  For the treatment of osteoporosis in patients with the inability to swallow.
- clopidogrel bisulfate, tablet, 75mg (Plavix-BMY)
  For the treatment of peripheral arterial disease in patients intolerant/allergic to ASA.

REVISED EDS CRITERIA:

The EDS criteria has been revised as follows for the following product:

- Formoterol fumarate dihydrate/budesonide, powder for inhalation, 6ug/100ug, 6ug/200ug (Symbicort-AST)
  a) Asthma in patients uncontrolled on inhaled steroid therapy.
  b) COPD in patients who are uncontrolled on a long-acting beta-2-agonist alone.

CURRENTLY UNDER REVIEW WITH THE NATIONAL COMMON DRUG REVIEW PROCESS (as of the printing of this Bulletin):

- adalimumab (Humira for Crohn's disease)
- delta-9-tetrahydrocannabidiol/ cannabinol (Sativex)
- entecavir (Baraclude)
- idursulfase (Elaprase)
- lanthanum carbonate hydrate (Fosrenol)
- posaconazole (Spriafil)
- ranibizumab (Lucentis)
- sitaxsentan sodium (Thelin)
- telbivudine (Sebivo)
- tramadol HCl (Zytram XL)

OTHER PRODUCTS CURRENTLY UNDER REVIEW BY THE SASKATCHEWAN REVIEW COMMITTEES:

- alglucosidase alfa, powder for solution, 50mg/vial (Myozyme-GZY)
- efalizumab, powder for solution, 150mg/vial (Raptiva-SRO)
- etanercept, powder for injection (vial), 25mg/vial; pre-filled syringe, 50mg/ml (Enbrel-AMG) (for the treatment of severe plaque psoriasis)
- infliximab, injection (mg),100mg/vial (Remicade-SCH) (for the treatment of severe plaque psoriasis)
- natalizumab, injection solution, 300mg/mL (Tysabri-BGN)

PRODUCTS NOT RECOMMENDED FOR COVERAGE VIA THE COMMON DRUG REVIEW (CDR) PROCESS:

The following products were reviewed by the Canadian Expert Drug Advisory Committee (CEDAC) under the national Common Drug Review (CDR) process and were not recommended for coverage under provincial drug plans. The CEDAC recommendations were supported by the Saskatchewan drug review process:

- lumiracoxib, tablet, 100mg (Prexige-NVR)
- penciclovir, topical cream, 1% (Denavir-BTI)
- tramadol/acetaminophen, tablet, 37.5mg/325mg (Tramacet-JAN)

For more information on the CDR please visit the website: www.cadth.ca/index.php/en/cdr/recommendations/search.

OTHER PRODUCTS NOT RECOMMENDED BY THE SASKATCHEWAN REVIEW COMMITTEES:

- adalimumab, solution for injection, pre-filled pen 40mg/0.8mL (Humira-ABB)
  NOT recommended as the Committee did not perceive a need for this form of the product.
- dorzolamide HCl, ophthalmic solution, 2% (preservative-free) Trusopt-MSD)
  NOT recommended due to a lack of evidence to support the need for a preservative-free formulation.
- gliclazide, modified release tablet, 30mg (Diamicron MR-SEV)
  This product was again reviewed and NOT recommended for coverage as it offers no demonstrated clinical advantage over listed products.
- infliximab, injection (mg),100mg/vial (Remicade-SCH) - psoriatic arthritis
  NOT recommended for the treatment of psoriatic arthritis as it offers no advantage over listed alternatives and is more expensive.
- methylphenidate, controlled-release capsule, 10mg, 15mg, 20mg, 30mg, 40mg, 50mg, 60mg (Biphentin-PFR)
  NOT recommended as it offers no clinical advantage over listed alternatives and it is difficult to justify the incremental cost.
- olanzapine, tablet, 20mg (Zyprexa-LIL)
  NOT recommended as the Committee sees no reason to add this product.

The following 3 drugs were reviewed for ankylosing spondylitis and NOT recommended:

- adalimumab, 40mg/0.8ml, pre-filled syringe (Humira-ABB) AND
- etanercept, powder for injection (vial), 25mg/vial; pre-filled syringe, 50mg/ml Enbrel-AMG) AND
- infliximab, 100mg/vial injection (MG) (Remicade-SCH)

These drugs were not recommended for listing for ankylosing spondylitis because the Saskatchewan review committees suggest the clinical benefit does not justify the incremental cost of these drugs.

NEW INTERCHANGEABLE LISTINGS EFFECTIVE JULY 1, 2007:

- acetylsalicylic acid, enteric coated tablet, 650mg (pms-ASA EC-PMS)
- fluticasone propionate, nasal spray, 50ug/actuation (ratio-Fluticasone 50 NS-RPH)
- levetiracetam, tablet, 250mg, 500mg, 750mg (pms-Levetiracetam-PMS)
- pravastatin, tablet, 10mg, 20mg, 40mg (Ran-Pravastatin-RAN)
- tamsulosin HCl, sustained release capsule, 0.4mg (Sandoz Tamsulosin-SDZ)

NEW INTERCHANGEABLE EDS LISTINGS EFFECTIVE AUGUST 1, 2007 ACCORDING TO CURRENT EDS CRITERIA:

- cefprozil, suspension, 25mg/mL, 50mg/mL (Apo-Cefprozil-APX)
- clarithromycin, tablet, 250mg, 500mg (Apo-Clarithromycin-APX)
- clarithromycin, tablet, 250mg, 500mg (Gen-Clarithromycin-GPM)
- clarithromycin, tablet, 250mg, 500mg (pms-Clarithromycin-PMS) (Aug 10/07)
- clarithromycin, tablet, 250mg, 500mg (ratio-Clarithromycin-RPH)

NEW INTERCHANGEABLE LISTINGS EFFECTIVE AUGUST 1, 2007:

- benazepril, tablet, 5mg, 10mg (Apo-Benazepril-APX)
- doxycycline, tablet & capsule, 100mg (pms-Doxycycline-PMS)

NEW INTERCHANGEABLE LISTING EFFECTIVE SEPTEMBER 1, 2007:

- acetylsalicylic acid, enteric coated tablet, 325mg (pms-ASA EC-PMS)
- metoprolol tartrate, sustained release tablet, 100mg, 200mg (Apo-Metoprolol SR-APX)
- topirimate, tablet, 25mg, 100mg, 200mg (CO Topirimate-COB)

NEW INTERCHANGEABLE EDS LISTINGS EFFECTIVE SEPTEMBER 1, 2007 ACCORDING TO CURRENT EDS CRITERIA:

- desmopressin, tablet, 0.1mg, 0.2mg (Novo-Desmopressin-NOP)

NEW INTERCHANGEABLE LISTING EFFECTIVE OCTOBER 1, 2007:

- tamsulosin HCl, sustained-release capsule, 0.4mg (Gen-Tamsulosin-GPM)
- venlafaxine HCl, sustained release capsule, 37.5mg, 75mg, 150mg (ratio-Venlafaxine XR-RPH)

FLOLAN will now be administered under the Exception Drug Status program subject to the family copayment under the Special Support program. The EDS criteria is: For the treatment of pulmonary hypertension on the recommendation of a specialist. Patients approved for coverage prior to September 1, 2007 will continue to receive the drug at no charge. Please contact the Drug Plan for billing details.

Pergolide (Permax)
Due to new safety information Eli Lilly in cooperation with Health Canada have stopped sales of Permax (pergolide mesylate) in Canada. While the manufacturer will not be able to sell Permax as of August 30, 2007, wholesales and pharmacies will be permitted to sell existing stock until supplies are either depleted or become outdated.

INFORMATION FROM COMPUS

The Canadian Optimal Medication Prescribing and Utilization Service (COMPUS), a directorate of the Canadian Agency for Drugs and Technologies in Health, is a collaborative, pan-Canadian service funded by Health Canada. Launched in 2004, COMPUS is a nationally coordinated program that identifies optimal therapies in drug prescribing and use, and promotes their use by policy makers, educators, health care providers and consumers. The program is one of only a handful of this nature in the world and the first pan-Canadian initiative established to support optimal drug therapy amongst these stakeholders.

PROTON PUMP INHIBITORS

COMPUS' first project addressed the use of proton pump inhibitors (PPIs) for the management of: gastroesophageal reflux disease (GERD), dyspepsia, and peptic ulcer disease (PUD). An expert review panel provided advice to the COMPUS program on the optimal prescribing and use of PPIs. The Panel was comprised of a variety of clinical practitioners with expertise in drug therapy and evaluation of evidence, including four gastroenterologists. The key findings from this project are:

→ All PPIs are equally efficacious in the initial treatment of GERD, dyspepsia and other common GI conditions.*

→ Doubling the standard daily doses of PPIs, as initial therapy, is no better than standard daily dose therapy.

→ PPIs are not efficacious in treating cough, asthma or laryngeal symptoms associated with GERD.

COMPUS has produced a number of clinical and optimal therapy reports on PPIs, together with user-friendly tools to support optimal PPI drug therapy. Examples of the tools include an alternate prescription pad, quick reference prescribing aid, didactic Power Point presentations, and a newsletter. Reports and tools are available online at www.cadth.ca.

** The key finding that all PPIs are equally efficacious is consistent with the Drug Plan's "Maximum Allowable Cost Policy for PPIs" that was established in 2004. For more information regarding the Maximum Allowable Cost Policy for PPIs, see Appendix I on page 276 of the Saskatchewan Formulary (57th edition).*

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FORMULARY AND EDS UPDATES EFFECTIVE OCTOBER 1, 2007

GENERIC & TRADE NAME	*STRENGTH & FORM*	*DIN*	*UNIT PRICE*	*LEGEND*
Abatacept				
Orencia	250mg/vial powder for solution	02282097	470.0000	EDS
Alendronate sodium				
Fosamax	70mg/mL oral solution	02248625	10.2860	EDS
Atazanavir SO4				
Reyataz	300mg capsule	02294176	21.3247	EDS
Blood glucose test strip				
Ascencia Breeze 2	blood glucose test strip	00950960	0.8680	Not I/C
Isopropyl myristate				
Resultz	50% topical solution	02279592	0.1041	
Lanreotide acetate				
Somatuline Autogel	60mg injection (per mg)	02283395	18.8700	EDS
Somatuline Autogel	90mg injection (per mg)	02283409	16.6700	EDS
Somatuline Autogel	120mg injection (per mg)	02283417	15.5900	EDS
Ramipril/hydrochlorothiazide				
Altace HCT	2.5mg/12.5mg tablet	02283131	0.4069	
Altace HCT	5mg/12.5mg tablet	02283158	0.4069	
Altace HCT	5mg/25mg tablet	02283174	0.4069	
Altace HCT	10mg/12.5mg tablet	02283166	0.5154	
Altace HCT	10mg/25mg tablet	02283182	0.5154	
Rituximab				
Rituxan	10mg/mL injection solution	02241927	51.8500	EDS
***Tamsulosin HCl**				
Gen-Tamsulosin	0.4mg sustained-release capsule	02298570	0.6510	I/C
Valsartan				
Diovan	320mg tablet	02289504	1.2068	
***Venlafaxine HCl**				
ratio-Venlafaxine XR	37.5mg capsule	02273969	0.6379	I/C
ratio-Venlafaxine XR	75mg capsule	02273977	1.2758	I/C
ratio-Venlafaxine XR	150mg capsule	02273985	1.3470	I/C

LEGEND: EDS-Exception Drug Status; I/C-Interchangeable; Not I/C-Not Interchangeable

Saskatchewan
Health

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Pharmacy Information
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FORMULARY UPDATES
NEW GENERICS

Effective **September *1, 2007*** under the generic streamlining policy, the following products will be listed as ***interchangeable*** with the currently listed brand(s):

GENERIC & TRADE NAME	***STRENGTH & FORM***	***DIN***	***UNIT PRICE***	***LEGEND***
***Acetylsalicylic acid**				
pms-ASA EC	325mg tablet	02284529	0.0304	I/C
***Desmopressin**				
Novo-Desmopressin	0.1mg tablet	02287730	1.0756	I/C EDS
Novo-Desmopressin	0.2mg tablet	02287749	2.1512	I/C EDS
***Metoprolol tartrate**				
Apo-Metoprolol SR	100mg SR tablet	02285169	0.2193	I/C
Apo-Metoprolol SR	200mg SR tablet	02285177	0.3980	I/C
***Topiramate**				
CO Topiramate	25mg tablet	02287765	0.7178	I/C
CO Topiramate	100mg tablet	02287773	1.3603	I/C
CO Topiramate	200mg tablet	02287781	2.1532	I/C

Effective **September 1, 2007** the following products will be available for coverage under Exception Drug Status subject to the indicated criteria.

***desmopressin, tablet, 0.1mg, 0.2mg (Novo-Desmopressin-NOP)**
For treatment of:

(a) Diabetes insipidus.
(b) Enuresis in children over 5 years of age refractory to bed-wetting alarms or alternative agents listed in the Formulary.
(c) Nocturia in patients with a recognized neurological disorder which causes detrusor over-activity confirmed by cystogram in the absence of obstruction, who have not responded or are intolerant to at least two anticholinergic drugs.

Cease Sale of Permax (pergolide mesylate) in Canada
Eli Lilly Canada Inc., in collaboration with Health Canada, advises Healthcare Professionals that sales of Permax will cease in Canada as of August 30, 2007 due to risk of cardiac valvulopathy. Eli Lilly Canada Inc. and Health Canada will allow wholesalers and pharmacies to deplete existing inventory allowing patients to transition to alternative anti-Parkinson therapies.

Pergolide mesylate

Permax	0.05mg tablet	02123320	0.2750
Permax	0.25mg tablet	02273977	1.0083
Permax	1mg tablet	02273985	3.4373

FORMULARY AND EDS UPDATES EFFECTIVE AUGUST 1, 2007

GENERIC & TRADE	*STRENGTH & FORM*	*DIN*	*UNIT*	*LEGEND*
***Benazepril HCl**				
Apo-Benazepril	5mg tablet	02290332	0.5491	I/C
Apo-Benazepril	10mg tablet	02290340	0.6490	I/C
***Cefprozil**				
Apo-Cefprozil	25mg/mL oral suspension	02293943	0.1201	I/C EDS
Apo-Cefprozil	50mg/mL oral suspension	02293951	0.2403	I/C EDS
***Clarithromycin**				
Gen-Clarithromycin	250mg tablet	02248856	1.1941	I/C EDS
Gen-Clarithromycin	500mg tablet	02248857	2.3880	I/C EDS
ratio-Clarithromycin	250mg tablet	02247818	1.1941	I/C EDS
ratio-Clarithromycin	500mg tablet	02247819	2.3880	I/C EDS
***Doxycycline**				
pms-Doxycycline	100mg capsule	02289539	0.6359	I/C
pms-Doxycycline	100mg tablet	02289466	0.6359	I/C

Effective **August 1, 2007** the following products will be available for coverage under Exception Drug Status subject to the indicated criteria.

***cefprozil, tablet, 250mg, 500mg; suspension, 25mg/mL, 50mg/mL (Apo-Cefprozil-APX) (Ran-Cefprozil-RAN)**

For treatment of:

(a) Upper and lower respiratory tract infections in patients unresponsive to first-line antibiotics.
(b) Infections caused by organisms known to be resistant or unresponsive to alternative antibiotics.
(c) Infections in patients allergic to alternative antibiotics. *(Note: patients who have had an* anaphylactic reaction to penicillin should not receive cephalosporins.)
(d) Respiratory tract infections in nursing home patients.
(e) Pneumonia in patients in the community with comorbidity e.g. chronic underlying lung disease (excluding asthma), diabetes mellitus, renal insufficiency, heart failure, stroke, and:
(f) For completion of antibiotic treatment initiated in hospital.

***clarithromycin, tablet, 250mg, 500mg, (Gen-Clarithromycin-GPM) (ratio-Clarithromycin-RPH)**

For treatment of:

(a) Pneumonia.
(b) Upper and lower respiratory tract bacterial infections known to be resistant to alternative antibiotics.
(c) Upper and lower respiratory tract bacterial infections unresponsive to alternative antibiotics.
(d) Infections in patients allergic to alternative antibiotics.
(e) For treatment (and prophylaxis) in patients with non-tuberculous Mycobacterium.
(f) For one week for eradication of *H. pylori* -related infections when used in combination treatment regimens for the treatment of peptic ulcer disease.
(g) For completion of treatment initiated in hospital with macrolides or quinolones.
(h) For patients intolerant to erythromycin and/or other antibiotics.

LEGEND: EDS-Exception Drug Status; I/C-Interchangeable; Not I/C-Not Interchangeable

CRITERIA FOR NEW EXCEPTION DRUG STATUS (EDS) ADDITIONS

EDS UPDATE EFFECTIVE OCTOBER 1, 2007

*Effective **October 1, 2006** the following products will be available for coverage under Exception Drug Status subject to the indicated criteria.*

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abatacept, powder for solution, 250mg/vial (Orencia-BMY)
For treatment of severely active rheumatoid arthritis when used in combination with DMARDs (unless these agents are contraindicated) in patients who have failed to respond to an adequate trial of an anti-TNF agent. This drug should **NOT** be used **in combination** with other anti-TND agents.

alendronate sodium, 70mg/mL (Fosamax-MSD)
For treatment of osteoporosis in patients with the inability to swallow.

atazanavir SO4, capsule 300mg (Reyataz-BMY)
For treatment of HIV disease. *This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.*

lanreotide acetate, injection, 60mg, 90mg, 120mg (Somatuline Autogel-TCI) Bill per mg
For treatment of acromegaly.

rituximab, injection solution, 10mg/mL (Rituxan-HLR)
For treatment of severe arthritis when used in combination with methotrexate in the treatment of adult patients who have failed to respond to an adequate trial of an anti-TNF agent. Rituxan should not be used concomitantly with anti-TNF agents.
Please call the Drug Plan for billing information.

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA

*Effective **October 1, 2007** criteria for the following product is modified as follows:*

clopidogrel bisulfate, tablet, 75mg (Plavix-SAW)
(f) For treatment of peripheral arterial disease in patients intolerant/allergic to ASA.

REVISIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA

*Effective **October 1, 2007** criteria for the following product is modified as follows:*
formoterol fumarate dihydrate/budesonide, powder for inhalation (package), 6ug/100ug, 6ig200ug (Symicort Turbuhaler-AST)
For treatment of:
(a) Asthma in patients uncontrolled on inhaled therapy.
(b) COPD in patients who are uncontrolled on a long-acting beta-2 agonist alone.